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ALZA CORPORATION

By: Henrietta Votaw

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|---|---|
| Applicant(s) | : | SOUTHAM, Mary et al. | ) |
| Serial No. | : | Not yet Assigned | ) Group Art Unit: Not Assigned |
| Filed | : | Evendate Herewith | ) Examiner: Not Assigned |
| For | : | Device for Transdermal Electrotransport Delivery of Fentanyl and Sufentanil | ) **PRELIMINARY AMENDMENT** |

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In the above-identified continuation application, before action thereon, kindly amend as follows:

**In the Specification**

On page 1, after the title, please insert --This is a continuation of US patent Application Serial No. 08/952,657 filed March 17, 1998.--

**In the Claims**

Kindly cancel all claims 1-20 and substitute therefor the following new claims:

21. A method of obtaining analgesia in a human patient who is suffering from pain, consisting of transdermally delivering solely by electrotransport a dose of

about 20 μg to about 60 μg of fentanyl over a predetermined delivery period of up to about 20 minutes, terminating said delivery at the end of said delivery period and thereafter repeating such transdermal administering up to about 100 additional of said doses over a period of 24 hours.

22. The method of claim 21, wherein about 35 μg to about 45 μg of fentanyl is delivered over a delivery period of about 5 to 15 minutes.

23. The method of claim 21, wherein about 40 μg of fentanyl is delivered over the delivery period.

24. The method of claim 21, wherein the delivery period is about 10 minutes.

25. The method of claim 21, wherein the additional doses are 35 μg to 45 μg doses of fentanyl.

26. The method of claim 21, wherein the fentanyl comprises a fentanyl salt.

27. The method of claim 26, wherein the fentanyl salt comprises fentanyl hydrochloride.

28. The method of claim 21, wherein the doses are self-administered by the patient suffering from pain.

29. The method of claim 28, wherein the patient is allowed to self-administer no more than six of said doses per hour.

30. A method of obtaining analgesia in a human patient who is suffering from pain, consisting of transdermally delivering solely by electrotransport a dose of

about 2.3 μg to about 7.0 μg of sufentanil over a predetermined delivery period of up to about 20 minutes, terminating said delivery at the end of said delivery period and thereafter repeating such transdermal administering up to about 100 additional of said doses over a period of 24 hours.

31. The method of claim 30, wherein about 4 μg to about 5.5 μg of sufentanil is delivered over a delivery period of about 5 to 15 minutes.

32. The method of claim 30, wherein about 4.7 μg of sufentanil is delivered over the delivery period.

33. The method of claim 30, wherein the delivery period is about 10 minutes.

34. The method of claim 30, wherein the additional doses are 4 μg to 5.5 μg doses of sufentanil.

35. The method of claim 30, wherein the sufentanil comprises a sufentanil salt.

36. The method of claim 35, wherein the sufentanil salt comprises sufentanil hydrochloride.

37. The method of claim 30, wherein the doses are self-administered by the patient suffering pain.

38. The method of claim 37, wherein the patient is allowed to self-administer no more than six of said doses per hour.

**Remarks**

Applicants submit herewith a new set of claims for consideration. The Examiner should review the allowed claims in the parent application (US Serial No. 08/952,657 filed March 17, 1998) to consider potential double patenting issues. An early and favorable action on the merits is respectfully requested.

Respectfully Submitted,

ALZA Corporation

Dated: February 7, 2001

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